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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Si Young Cho

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EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/599,290	<b>Applicant(s)</b> CHO ET AL.
	<b>Examiner</b> BAHAR SCHMIDTMANN	<b>Art Unit</b> 1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 8-11 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/28/2010</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 July 2010 has been entered.

This Office Action is in response to Applicant's Amendment and Remarks filed on 11 June 2010 in which claims 3, 6 and 7 were canceled, claims 1, 4 and 8-10 were amended to change the scope and breadth of the claims, and claim 11 was newly added.

Claims 1, 2, 4, 5 and 8-11 are pending in the current application and are examined on the merits herein.

### ***Withdrawn Rejections***

The rejection of claim 1 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 12/064887 in view of Lee et al. (*J. of Invest. Dermat.*, cited in previous Office Action) is hereby **withdrawn**. It is noted that a restriction requirement between the composition comprising EGCG and the method of using a composition comprising EGCG was made. Applicants elected the method of using the composition and the claims directed to the composition itself were canceled.

### ***New Rejections and Objections***

The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed on 11 June 2010, where the limitations in pending claims 1, 2, 4, 5 and 8-10 as amended now have been changed, and claim 11 is newly added. Therefore, rejections from the previous Office Action, dated 15 March 2011, have been modified and are listed below.

### ***Claim Objections***

Claim 1, 2, 4, 5 and 11 are objected to because of the following informalities: The recitation "range of 1:**01**-1:10" on line 4 of claim 1 appears to be a typographical error. Independent claims 8, 9 and 10 all recite "range of 1:**0.1**-1:10". Claims 2, 4, 5 and 11 depend from independent claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 2, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The recitation "wherein said skin-care is obtained by the apoptosis-inhibitory effect of said active ingredients" in claim 2 renders the claim and its dependent claims 4

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and 5 herein indefinite. It is unclear if the "skin care" obtained refers to ginsenoside F1 or if it refers to EGCG or if it refers to both ginsenoside F1 and EGCG.

It is also understood that apoptosis is a cellular event. Therefore, it is unclear what cells are prevented from undergoing apoptosis (i.e. apoptosis-inhibitory effect) such that ginsenoside F1 and/or EGCG are produced. The claim as currently written appears to be a product-by-process claim. However, it appears that ginsenoside F1 is not a by-product of an apoptosis inhibitor effect. Rather, ginsenoside F1 is an apoptosis inhibitor. As evidenced by Lee et al. (*J. of Invest. Dermat.*, cited in previous Office Actions), ginsenoside F1 is suggested to protect cells against UVB induced apoptosis by maintaining constant levels of Brn-3a and inhibiting Bcl-2 down regulation (p.607, second column, second paragraph). Therefore, it appears that claims 2, 4 and 5 should be clarified such that they are not product-by-process limitations and instead the property of the ginsenoside F1.

The recitation "Bcl-2" in claim 4 and "Brn-3a" in claim 5 render the claims herein indefinite. Acronyms or abbreviations can be interpreted differently depending on the context and the art. For example, "EPA" can stand for "eicosapentaenoic acid" or it can be an abbreviation for the "Environmental Protection Agency". Thus, it is unclear whether "Bcl-2" refers to "B-cell lymphoma 2," or whether it is an acronym or abbreviation for something else. To render the claim definite, it is respectfully suggested that Applicants spell out what they intend to claim or clearly identify the claimed agents, rather than use acronyms or abbreviations. If Applicants intend to use

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acronyms or abbreviations in the claims, it is respectfully suggested that the acronym or abbreviation first be spelled out along with the acronym where it is first used in a claim before use of the acronym or abbreviation in subsequent claims.

Clarification is requested.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 2, 4, 5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoo et al. (EP 1327434: published July 2003; cited by Applicant in Information Disclosure Statement submitted 01 July 2009) in view of Ahn et al. (KR10-2003-0075492: published September 2003; machine translation cited in**

**PTO-892) and Park et al. (KR10-2003-0064986: published August 2003; machine translation cited in previous Office Action) as evidenced by Lee et al. (*J. of Invest. Dermat.*, cited in previous Office Actions)**

Yoo et al. teaches a composition comprising 5-25 wt.% ginsenoside F1 (20-O- $\beta$ -D-glucopyranosyl-20(S)-protopanaxatriol), (claim 3 and abstract) in an admixture of ginseng saponin metabolites. Yoo et al. the ginseng saponin metabolite, i.e. the ginsenoside F1, can be present in an amount of 0.001-30% by weight on the total weight of the overall composition (claim 5). Yoo et al. teaches an example formulation comprising 1.5% by weight ginsenoside F1 (see p.9, table 1, example 3). Yoo et al. also teaches an example formulation comprising 1.5% by weight Bio GF1K (which comprises the ginsenoside F1, see page 7, paragraph 0054 for description of Bio GF1K) with 0.2% by weight  $\alpha$ -tocopherol and 0.01% butylated hydroxyl toluene (also known as BHT; see p.9, table 1, example 5). Yoo et al. teaches BHT was added as an antioxidant (p.7, paragraph 0060).

Yoo et al. describes six examples for preparing Bio GF1K, wherein ginsenoside F1 was obtained as an admixture of ginseng saponin metabolites (p.5-7). Yoo et al. teaches in reference example 2, ginsenoside F1 was obtained as 22 percent by weight of the admixture. Therefore, an overall skin care composition comprising 1.5% admixture actually comprises 0.33% by weight ginsenoside F1 based on the weight of the overall composition. A table summarizing these values is provided below.

	Reference Example 2	Reference Example 3	Reference Example 4-1	Reference Example 4-2	Reference Example 4-3	Reference Example 4-4
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% by wt. based on wt. admixture	30 mg per 135 mg total admixture = 22%	35 mg per 140 mg total admixture = 25%	150 mg per 730 mg total admixture = 20.5%	100 mg per 352 mg total admixture = 28%	30 mg per 145 mg total admixture = 21%	82 mg per 347 mg total admixture = 24%
% by wt. based on total composition	0.22 * 1.5% = 0.33%	0.25% * 1.5% = 0.38%	0.205 * 1.5% = 0.31%	0.28 * 1.5% = 0.43%	0.21 * 1.5% = 0.31%	0.24 * 1.5% = 0.35%
Ratio of Ginsenoside F1: antioxidant (0.201%)	1.6:1	1.9:1	1.5:1	2.1:1	1.5:1	1.7:1

Yoo et al. teaches the composition is useful in skin-care for anti-aging (claim 15).

Yoo et al. does not expressly disclose (-)epigallocatechin-3-gallate (EGCG) as an anti-oxidant (instant claim 1).

Ahn et al. teaches a cosmetic composition comprising EGCG that inhibits aging of the skin (abstract). Ahn et al. suggests EGCG inhibits oxidation of the skin from oxygen and inhibits peroxide formation (abstract). Ahn et al. teaches a cosmetic composition comprising 0.001 to 20 wt % EGCG (abstract). Ahn et al. teaches EGCG is preferably used in an amount of 0.01 to 5 wt% (p.6 of machine translation, second paragraph). Ahn et al. also teaches two examples wherein 1 wt.% EGCG is embodied (pp.6-7 of machine translation, testing examples 1 and 2).



Park et al. teaches a cosmetic composition comprising physiologically active compounds (p.2, *Purpose of the invention*, first paragraph). Park et al. teaches the physiologically active compounds include EGCG and ginsenosides (p.4, third paragraph).

It would have been obvious at the time the invention was made to formulate ginsenoside F1 with EGCG at a ratio of 1:0.1-1:10, wherein the amount of ginsenoside F1 and EGCG are incorporated in a combined amount of 0.0001% to 10% by weight.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

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(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Based on the teachings of the MPEP and KSR above, by employing the rationale in (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate ginsenoside F1 with EGCG at a ratio of 1:0.1-1:10, wherein the amount of ginsenoside F1 and EGCG are incorporated in a combined amount of 0.0001% to 10% by weight.

From Park et al., one having ordinary skill in the art would have known at the time the invention was made that ginsenoside and EGCG can be combined together in the same cosmetic formulation. Additionally, Yoo et al. teaches ginsenosides and antioxidants can be prepared together in the same skin-care composition and Ahn et al. teaches the antioxidant EGCG can be formulated in cosmetic skin care compositions. Thus, because their combination is expressly taught and suggested by the prior art, it

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would have been obvious at the time the invention was made to combine them together in a skin care composition.

Because Yoo et al. teaches anti-oxidants can be combined at specific amounts relative to ginsenoside, and because Park teaches ginsenoside combined with EGCG, it would have been obvious at the time the invention was made to combine the teachings of Yoo et al. with Ahn et al. or to substitute the anti-oxidants taught by Yoo et al. with EGCG with a reasonable expectation of producing a skin-care product.

According to MPEP 21440.03: In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)

From Yoo et al., one having ordinary skill in the art would have known at the time the invention was made that ginsenoside F1 can be formulated at 0.001-30% by weight with 0.201% by weight antioxidant (antioxidants are  $\alpha$ -tocopherol and BHT). This encompasses a ratio of ginsenoside F1 to EGCG of 1:7, for example 0.04:0.2 (ginsenoside F1 to EGCG), is equivalent to 1:5. Yoo et al. also provides expressed embodiments wherein the range of ginsenoside F1 to EGCG is 1.5:1, and wherein the composition comprises 0.31-0.43% by weight ginsenoside F1 and 0.201% by weight antioxidant based on the total weight of the composition. This provides a combined amount of 0.51-0.63% by weight ginsenoside F1 and antioxidant. Additionally, Ahn et al. teaches EGCG can be formulated in a cosmetic composition at 0.01 to 5% by weight of the total composition, which is consistent with the amount of antioxidant taught by Yoo et al.

The “wherein” limitations of instant claims 2, 4 and 5 appear to be the inherent properties of ginsenoside F1 as evidenced by Lee et al. Lee et al. teaches ginsenoside F1 protects cells against UVB induced apoptosis by maintaining constant levels of Brn-3a and inhibiting Bcl-2 down regulation (p.607, second column, second paragraph). Lee et al. teaches UVB causes said Bcl-2 down regulation via down regulation of said Brn-3a transcription factor in human HaCaT keratinocytes (p.607, second column, second paragraph). Lee et al. teaches ginsenoside F1 as a useful compound in preventing UVB-induced skin damage (p.612, second column, final paragraph).

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4, 5 and 8-11 have been considered but are moot in view of the new ground(s) of rejection.

I. Applicant has argued that the claims have been amended to define a scope commensurate with the “unexpected results” described in the 132 Declaration by Ms. Cho.

However, in view of the new ground(s) of rejection above, this is not found persuasive to overcome the obviousness rejection.

(a) The declaration only provides one ratio of ginsenoside F1 to EGCG, wherein the concentrations are described as micromolar and not as percent by weight based on the total weight of the composition as instantly claimed. Instant claims 1 and 8-10

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encompass a much larger ratio. And as seen from the Yoo et al. reference, it would have been obvious to provide a ratio of ginsenoside F1 to antioxidant that lies within the instantly claimed ranges. Instant claim 11 is drawn to ginsenoside F1 and EGCG in a 1:5 weight ratio wherein together they represent 0.0001% to 10% by weight of the composition based on the total weight of the composition. However, it is unclear how the combined ginsenoside F1 and EGCG weight of 0.0001% to 10% based on the total weight of the composition is related to 2  $\mu$ M ginsenoside F1 and 10  $\mu$ M EGCG described in the 132 Declaration of Ms. Cho.

Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963). Applicant has the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974).

(b) Also, without additional data and without a comparison to the expressed values taught by Yoo et al., it is unclear if the results are truly unexpected. There are no other ratios or concentrations to compare the results to, and thus no trend can be discerned. It is unclear if 1:5 is unexpectedly better since no other ratios are provided, and the ratio of 1:5 is only provided in combination with 2  $\mu$ M ginsenoside F1 and 10  $\mu$ M EGCG instead of various points along the claimed combined amount of 0.0001% to 10% based on the total weight of the composition. The example in the 132 Declaration of Ms. Cho provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art. Additionally, the newly cited prior art suggests a ratio that encompasses the instantly claimed ratios. According to MPEP

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716.02, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus, the evidence in the 132 Declaration is still not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed weight ratio and combined amount of the ingredients in the claimed composition. See MPEP § 716.02(d). Therefore, the evidence presented in specification and the 132 Declaration herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

The rejection is hereby **maintained**.

**Claims 1, 2, 4, 5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeom et al. (*Cosmetics & Toiletries*, published May 2003, vol. 118, no. 3, pp.77-80 and 82, cited in PTO-892) and Ahn et al. (cited above) in view of Park et al. (cited above) as evidenced by Lee et al. (cited above).**

Yeom et al. teaches hydrolyzed ginseng saponins contains high concentration of ginsenoside F1 (p.77, last paragraph). Yeom et al. teaches isolating pure ginsenoside F1 (p.78, last paragraph). Yeom et al. teaches hydrolyzed ginseng saponins contain more than 7% ginsenoside F1 (p.79, first paragraph). Yeom et al. teaches 1%

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hydrolyzed ginseng saponins increased total collagen synthesis in normal human skin fibroblasts (p.79, third paragraph). Yeom et al. suggests the composition containing ginsenoside F1 can be used as an anti-wrinkle agent for the skin (p.79, "Anti-Wrinkle Activity on Skin") and as an anti-aging formulation (p.82, last paragraph).

Yeom et al. does not expressly disclose a skin-care composition comprising (-) epigallocatechin-3-gallate, hereafter EGCG (instant claims 1, 4, 5 and 8-11).

Ahn et al. teaches a cosmetic composition comprising EGCG that inhibits aging of the skin (abstract). Ahn et al. suggests EGCG inhibits oxidation of the skin from oxygen and inhibits peroxide formation (abstract). Ahn et al. teaches a cosmetic composition comprising 0.001 to 20 wt % EGCG (abstract). Ahn et al. teaches EGCG is preferably used in an amount of 0.01 to 5 wt% (p.6 of machine translation, second paragraph). Ahn et al. also teaches two examples wherein 1 wt.% EGCG is embodied (pp.6-7 of machine translation, testing examples 1 and 2).

Park et al. teaches a cosmetic composition comprising physiologically active compounds (p.2, *Purpose of the invention*, first paragraph). Park et al. teaches the physiologically active compounds include EGCG and ginsenosides (p.4, third paragraph).

It would have been obvious at the time the invention was made to formulate a skin-care composition comprising ginsenoside F1 and EGCG.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable

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results; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate a skin-care composition comprising ginsenoside F1 and EGCG.

From Park et al., one having ordinary skill in the art would have known that ginsenosides and EGCG can be combined together as active agents in a cosmetic composition. Additionally, Yeom et al. teaches isolating ginsenoside F1 and found that 1% hydrolyzed ginseng saponin comprising at least 7% of said ginsenoside F1 can be effective in skin care products. This provides a composition that has at least 0.07% by weight ginsenoside F1 based on the total weight of the composition. One having ordinary skill in the art would have also known from Ahn et al. that EGCG can be used as an anti-oxidant in a cosmetic composition at a range of 0.01 to 5 wt.% based on the total weight of the composition.

Because the art expressly suggests ginsenoside and EGCG can be combined together as active ingredients in a skin care composition, and Yeom et al. and Ahn et al. similarly teach ginsenoside F1 and EGCG can be used in skin care compositions, respectively, combining them together into the same formulation would have been obvious at the time the invention was made.

Furthermore, from Yeom et al., one having ordinary skill in the art would have known that at the very least a composition comprising at least 0.07% by weight ginsenoside F1 can be effective in treating the skin. Knowing that skin care products



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can also comprise 0.01 to 5 wt.% EGCG, one would have known that ginsenoside F1 and EGCG can be formulated in a weight ratio of 1:0.14 - 1:71. Thus, the weight ratio suggested by the combination of Yeom et al. and Ahn et al. overlaps with the instant claims. More specifically, one would have known that 1 wt.% EGCG is expressly embodied and that ginsenoside F1 and EGCG can be formulated in a weight ratio of 1:14. Thus, a person having ordinary skill in the art would have been motivated to utilize more EGCG relative to ginsenoside F1.

“In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990).” See MPEP 2144.05, section I.

Furthermore, one would have been motivated to combine both components because not only have they been proven useful on the skin, but the skin is also exposed to oxygen. Thus, one having ordinary skill would predict that a composition comprising both ginsenoside F1 and EGCG would successfully result in protecting the skin as a skin-care formulation.

The “wherein” limitations of instant claims 2, 4 and 5 appear to be the inherent properties of ginsenoside F1 as evidenced by Lee et al. Lee et al. teaches ginsenoside F1 protects cells against UVB induced apoptosis by maintaining constant levels of Brn-3a and inhibiting Bcl-2 down regulation (p.607, second column, second paragraph). Lee et al. teaches UVB causes said Bcl-2 down regulation via down regulation of said Brn-3a transcription factor in human HaCaT keratinocytes (p.607, second column,

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second paragraph). Lee et al. teaches ginsenoside F1 as a useful compound in preventing UVB-induced skin damage (p.612, second column, final paragraph).

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4, 5 and 8-11 have been considered but are moot in view of the new ground(s) of rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1, 2, 4, 5 and 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 and 7 of copending Application No. **10/586973** in view of Yoo et al. (cited above) and Ahn et al. (cited above).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 6-7 of the '973 application are drawn to a method for inhibiting biosynthesis of gelatinase comprising applying a composition comprising ginsenoside F1 and compound K.

The claims of the '973 application do not expressly disclose EGCG as part of the composition.

Yoo et al. teaches as discussed above.

Ahn et al. teaches as discussed above.

The obviousness rational for formulating a composition at the instantly claimed weight percent and ratios is the same as discussed above.

Thus, claims 1, 2, 4, 5 and 8-11 are *prima facie* obvious over claims 6 and 7 of the '973 application.

This is a provisional obviousness-type double patenting rejection.

II. Claims 1, 2, 4, 5 and 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 18-21 of copending Application No. **11/443271** in view of Yoo et al. (cited above) and Ahn et al. (cited above).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 16 and 18-21 of the '271 application are drawn to a method of combating aging comprising topically applying a nanoemulsion that comprises a ginseng glucoside. Claim 16 of the '271 lists 20-O- $\beta$ -D-glucopyranosyl-20(S)-protopanaxatriol (i.e. same as ginsenoside F1) as a ginseng glucoside.

The '271 application does not expressly disclose EGCG.

Yoo et al. teaches as discussed above.

Ahn et al. teaches as discussed above.

The obviousness rational for formulating a composition at the instantly claimed weight percent and ratios is the same as discussed above.

Thus, claims 1, 2, 4, 5 and 8-11 are *prima facie* obvious over claims 16 and 18-21 of the '271 application.

This is a provisional obviousness-type double patenting rejection.

III. Claims 1, 2, 4, 5 and 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-10 of copending Application No. **12/135,663** in view of Yoo et al. (cited above) and Ahn et al. (cited above).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '663 application are drawn to a method of administering a composition comprising ginsenoside F1 to prevent skin-aging or skin cancer.

The claims of the '663 application do not expressly disclose EGCG as part of the composition.

Yoo et al. teaches as discussed above.

Ahn et al. teaches as discussed above.

The obviousness rational for formulating a composition at the instantly claimed weight percent and ratios is the same as discussed above.

Thus, claims 1, 2, 4, 5 and 8-11 are *prima facie* obvious over claims 7-10 of the '663 application.

This is a provisional obviousness-type double patenting rejection.

IV. Claims 1, 2, 4, 5 and 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-23 of copending Application No. **12/740212** in view of Yoo et al. (cited above) and Ahn et al. (cited above).

The claims of the '212 application are drawn to a cosmetic composition and method of applying to the skin a composition comprising 0.0001-10 wt.% ginsenoside based on the total weight of the composition.

The claims of the '212 application do not expressly disclose EGCG.

Yoo et al. teaches as discussed above.

Ahn et al. teaches as discussed above.

The obviousness rational for formulating a composition at the instantly claimed weight percent and ratios is the same as discussed above.

Thus, claims 1, 2, 4, 5 and 8-11 are *prima facie* obvious over claims 12-23 of the '212 application.

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

Applicant's arguments filed 11 June 2010 have been fully considered but they are not persuasive.

Applicant has requested that the provisional rejections be held in abeyance until patentable subject matter is identified. However, this request cannot be considered, especially in view that no patentable subject matter has yet been identified.

The obviousness double patenting rejections are hereby **maintained**.

### ***Conclusion***

In view of the rejections to the pending claims set forth above, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is (571)270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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